DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Globus Medical, Incorporated
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

April 9, 2015

Re: K142218
Trade/Device Name: COALITION AGX™ Plate and COALITION AGX™ Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, KWQ
Dated: March 31, 2015
Received: March 31, 2015

Dear Dr. Baker:

This letter corrects our substantially equivalent letter of March 31, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142218

Device Name
COALITION AGX™ Plate and COALITION AGX™ Spacer

Indications for Use *(Describe)*
The COALITION AGX™ Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

The COALITION AGX™ Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-TI) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The COALITION AGX™ Spacer is to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation such as the COALITION AGX™ Plate, ASSURE®, PROVIDENCE™, VIP®, XTEND®, or UNIFY™ Anterior Cervical Plate Systems. When used with the COALITION AGX™ Plate, the assembly takes on the indications for use of the COALITION AGX™ Spacer, with the COALITION AGX™ Plate acting as the supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY: COALITION AGX™ System

Company:
Globus Medical Inc.
2560 General Armistead Avenue
Audubon, PA 19403
(610) 930-1800

Contact:
Kelly Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared:
March 23, 2015

Device Name:
COALITION AGX™ Plate and COALITION AGX™ Spacer

Classification:
21CFR §888.3080 Intervertebral Body Fusion Devices
21CFR §888.3080 Intervertebral Fusion Device with Integrated Fixation, Cervical
Product Codes: ODP, OVE
Regulatory Class: II; Panel Code: 87

21CFR §888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Code: KWQ
Regulatory Class: II; Panel Code: 87

Primary Predicate:
SUSTAIN® Radiolucent Medium (K130478)

Additional Predicates:
VIP® Anterior Cervical Plate System (K081391)
InterPlate™ C (K092070)
IN:C2™ Spinal Fixation System (K122630)
PEEK Prevail® Cervical Interbody Device (K073285)
PATRIOT® Colonial® ACDF Spacer (K072991)
COALITION® Spacer (K083389)

Purpose:
The purpose of this submission is to request clearance for the COALITION AGX™ Plate and COALITION AGX™ Spacer.

Device Description:
The COALITION AGX™ Plate is an anterior, cervical fixation device available in various heights and widths to fit the anatomical needs of a wide variety of patients. The plates are made from titanium alloy, as specified in ASTM F136, F1295, and F1472. The screws for use with the COALITION AGX™ Plates are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

COALITION AGX™ Spacers are anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and footprints to fit the anatomical needs of a wide variety of patients. These devices are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. The COALITION AGX™ Spacers are manufactured from radiolucent PEEK polymer, with titanium alloy or tantalum markers, as specified in ASTM, F2026, F136, F1295, F1472, and F560.

Indications for Use:
The COALITION AGX™ Plate is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

The COALITION AGX™ Spacer is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The COALITION AGX™ Spacer is to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the COALITION AGX™ Plate, ASSURE®, PROVIDENCE™, VIP®, XTEND®, or UNIFY™ Anterior Cervical Plate Systems. When used with the COALITION AGX™ Plate, the assembly takes on the indications for use of the COALITION AGX™ Spacer, with the COALITION AGX™ Plate acting as the supplemental fixation.

Performance Data:
Mechanical testing for the COALITION AGX™ Plate (static and dynamic compression bend, and static torsion), for the COALITION AGX™ Spacer (static and dynamic compression, static and dynamic compression-shear, static and dynamic torsion, and subsidence), and for the COALITION AGX™ Plate and Spacer (static compression, compression-shear, torsion, expulsion, subsidence, and plate pull-off) was conducted in accordance with the Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s (May 3, 2004) and ASTM F1717, F2077 and F2267, as applicable. Design validation/cadaver testing was conducted to ensure the COALITION AGX™ System performance is acceptable for its intended use and to ensure substantial equivalence to the predicate(s). Biomechanical cadaveric testing was also conducted. Performance and comparative analysis data demonstrate substantial equivalence to the predicate device(s).

Basis for Substantial Equivalence:
COALITION AGX™ implants are similar to the predicate devices with respect to technical characteristics, performance, design, materials, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. COALITION AGX™ implants are as safe, as effective, and perform as well as or better than predicate devices.